



UNITED STATES PATENT AND TRADEMARK OFFICE

UNITED STATES DEPARTMENT OF COMMERCE
United States Patent and Trademark Office
Address: COMMISSIONER FOR PATENTS
P.O. Box 1450
Alexandria, Virginia 22313-1450
www.uspto.gov

yo

APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/009,013	08/19/2004	Geir Olve Skeie	53550.40	2173

7590 04/05/2007
Francis C Hand
Carella Byrne Gilfillan Cecchi Stewart & Olstein
5 Becker Farm Road
Roseland, NJ 07068

EXAMINER

VENCI, DAVID J

ART UNIT	PAPER NUMBER
----------	--------------

1641

SHORTENED STATUTORY PERIOD OF RESPONSE	MAIL DATE	DELIVERY MODE
31 DAYS	04/05/2007	PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

If NO period for reply is specified above, the maximum statutory period will apply and will expire 6 MONTHS from the mailing date of this communication.

Office Action Summary	Application No.	Applicant(s)	
	10/009,013	SKEIE ET AL.	
	Examiner	Art Unit	
	David J. Venci	1641	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 1 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on September 12, 2005.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-8 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☐ Claim(s) _____ is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☒ Claim(s) 1-8 are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. _____ |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____ |

Art Unit: 1641

Election/Restrictions

This application contains inventions that are not linked to form a single general inventive concept under PCT Rule 13.1. In reply to this Office Action, Applicant is required to elect a single invention to which the claims must be restricted under 35 U.S.C. §§ 121 and 372, and 37 CFR § 1.499.

- I. Claims 1 and 2, drawn to a method of detecting ryanodine receptor antibodies
- II. Claims 3-6, drawn to a composition and kit
- III. Claims 2 and 7, drawn to a method of making a pharmaceutical composition
- IV. Claims 2 and 8, drawn to a method of prognosticating myasthenia gravis

According to PCT Rule 13.2, unity of invention exists only when the shared same or corresponding technical feature is a contribution over the prior art.

Here, the products of Invention II are used in the methods of Inventions (I or III or IV). The special technical feature linking Inventions I, II, III and IV appears to be a fusion protein "pc2" or "pc25". However, the technical feature linking Inventions I, II, III and IV does not constitute a special technical feature as defined by PCT Rule 13.2 because the technical feature does not define a contribution over the prior art. Treves *et al.*, 291 BIOCHEM. J. 757 (1993), also teach a fusion protein "pc2" (see Fig. 1). Therefore, unity of invention is lacking because the technical feature linking Inventions I, II, III and IV does not constitute a special technical feature as defined by PCT Rule 13.2, as it does not define a contribution over the prior art.

This application contains claims directed to the following species belonging to a generic invention:

- A. Select ONE protein sequence from:

Art Unit: 1641

1. SEQ. ID. NO:1; OR
2. SEQ. ID. NO:2.

Applicant is required to elect for prosecution a single species (*i.e.*, either A(1) or A(2)) to which the claims shall be restricted if no generic claim is finally held allowable. Currently, claims 1-3 and 6-8 are generic.

The species lack unity of invention because the species are not linked to form a single general inventive concept under PCT Rule 13.1 because, under PCT Rule 13.2, the species lack the same or corresponding special technical feature. Specifically, the species have different chemical structures.

Upon allowance of a generic claim, applicant will be entitled to consideration of claims to additional species which depend from or otherwise require all the limitations of an allowable generic claim as provided by 37 CFR 1.141. If claims are added after the election, applicant must indicate which are readable upon the elected species. MPEP § 809.02(a).

Applicant is advised that a complete reply to this requirement must include: (i) an election of an Invention and species to be examined even if the requirement is traversed¹ (37 CFR 1.143), and (ii) identification of the claims encompassing the elected invention and species. An argument that claims are allowable or that all claims are generic is considered non-responsive unless accompanied by an election.

Examiner notified Applicant's representative's assistant (*i.e.*, Attorney Francis Hand's assistant) of the instant Office Action during a telephone call on March 13, 2007. The telephone call did not result in an election.

¹ Applicant may elect an invention or species with traverse or without traverse. To reserve a right to petition, Applicant must elect with traverse. Should Applicant traverse on the ground that the inventions or species are not patentably distinct, Applicant should clearly admit on the record, or submit or identify evidence on the record that the inventions or species are obvious variants. If Examiner finds one Inventions unpatentable over the prior art, Examiner may use the evidence or admission of record to reject other inventions under 35 U.S.C.103(a).


Art Unit: 1641

Any inquiry concerning this communication or earlier communications from the examiner should be directed to David J. Venci whose telephone number is 571-272-2879. The examiner can normally be reached on 08:00 - 16:30 (EST). If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Long Le can be reached on 571-272-0823. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

David J Venci
Examiner
Art Unit 1641

djv


LONG V. LE 03/30/07
SUPERVISORY PATENT EXAMINER
TECHNOLOGY CENTER 1600